

**What is Claimed:**

1. A process for producing a cleaned cut bone graft suitable for transplantation into a human, comprising:

centrifuging a cut bone graft under conditions effective to remove bone marrow from cancellous bone spaces of said cut bone graft.

2. A process for cleaning a cut bone graft, comprising:

selecting a substantially intact bone;

cutting said substantially intact bone into one or more cut bone grafts; and

centrifuging said cut bone graft under conditions sufficient to remove bone marrow from cancellous bone spaces of said cut bone graft.

3. The process according to any one of claims 1 or 2, further comprising: prior to said step of centrifuging, pre-cleaning said cut bone graft in a pre-cleaning solution to produce a pre-cleaned cut bone graft.

4. The process according to claim 3, further comprising: after said step of pre-cleaning, cleaning said pre-cleaned cut bone graft in a first cleaning solution to produce a first cleaned bone graft.

5. The process according to claim 4, further comprising: after said step of centrifuging, second cleaning said cut bone graft in a second cleaning solution to produce a second cleaned cut bone graft.

6. The process according to claim 5, further comprising: optionally, after said step of second cleaning, <sup>first</sup> washing said second cleaned cut bone graft with a first washing solution to produce a first washed cut bone graft.

7. The process according to claim 6, further comprising: optionally, after said step of <sup>first</sup> washing, second washing said first washed bone graft with a second washing solution to produce a second washed bone graft.

8. The process according to claim 3, wherein said pre-cleaning solution comprises one or more members selected from the group consisting of <sup>or</sup> water, saline, an alcohol, and hydrogen peroxide.

9. The process according to claim 8, wherein said pre-cleaning solution further comprises one or more members selected from the group consisting of: an antiviral agent, an antibacterial agent, and an antifungal agent.

10. The process according to claim 4, wherein said first cleaning solution comprises one or more members selected from the group consisting of: water, <sup>alcohol</sup> saline, a decontaminating agent, a permeation enhancer, an amphiphilic component, an organic acid, and a dilute solution of one or more strong acids.

11. The process according to claim 5, wherein said second cleaning solution comprises one or more members selected from the group consisting of: water, <sup>alcohol</sup> saline, a decontaminating agent, an antiviral agent, a permeation enhancer, an amphiphilic compound, an organic acid, and a dilute solution of one or more strong acids.

12. <sup>The</sup> A process according to claim 4, wherein said pre-cleaning comprises pulsatile lavage or agitation.

13. The process of claim 12, wherein said agitation is performed in a paint can shaker at from 300 to 700 rpm for a time period of at least 5 minutes.

14. The process according to claim 6, wherein said first washing solution comprises a decontaminating agent.

a 15. The process according to claim 7, further comprising: <sup>second</sup> centrifuging said second washed bone graft to produce a cleaned bone graft essentially free from bone marrow.

a 16. The process according to claim 15, further comprising: prior to said step of <sup>second</sup> centrifuging and after said step of second washing, <sup>second</sup> ~~fifth~~ incubating said second washed bone graft in a solution comprising water.

a 17. The process according to claim 5, wherein said step of <sup>second cleaning</sup> ~~first incubating~~ comprises sonication.

a 18. The process according to claim 6, wherein said step of <sup>first washing</sup> ~~second incubating~~ comprises sonication.

a 19. The process according to any <sup>one</sup> of claims 6 or 14, further comprising: after said step of <sup>first washing, first</sup> ~~second incubating, third incubating~~ said first washed cut bone graft in said first washing solution for a time period of at least 6 hours.

a 20. The process according to claim 19, wherein said <sup>first</sup> ~~third~~ incubating comprises soaking.

15 21. The process according to claim 3, further comprising collecting waste solution in a disposable container.

22. The process according to claim 21, further comprising adding at least one strong viral or bacterial inactivator to said waste solution.

a 20 23. The process according to any one of claims ~~9~~ 10 or 11, wherein said amphiphilic component comprises one or more detergents.

Sub  
a4

24. The process according to any one of claims 9, 10 or 11, wherein said first or said second cleaning solution comprises Allowash™ solution.

25. The process according to claim 24, wherein said Allowash™ solution is at a concentration of between <sup>10.0%</sup>~~0.1%~~ and <sup>0.1%</sup>~~0.001%~~.

26. The process according to claim 25, wherein Allowash™ solution is at a concentration of <sup>0.1%</sup>~~0.01%~~.

27. The process according to claim 2, further comprising: prior to said step of cutting, removing bone marrow from a luminal space of said substantially intact bone.

28. The process according to claim 23, wherein said amphiphilic component comprises at least one solvent selected from the group consisting of: an anionic detergent, a cationic detergent, and non-ionic detergent and/or a non-anionic detergent.

29. The process according to any one of claims 9, 10 or 11, wherein said alcohol comprises ethanol.

30. The process according to claim 28, wherein said amphiphilic component comprises at least one solvent selected from the group consisting of: a polyoxyethylene alcohol, a polyethylene glycol p-isooctylphenylether, polyoxyethylene nonylphenol, and a polyoxyethylene sorbitol ester.

31. The process according to claim 29, wherein said second cleaning solution comprises at least one solvent selected from the group consisting of: a polyoxyethylene alcohol, a polyethylene glycol p-isooctylphenylether, polyoxyethylene nonylphenol, and a polyoxyethylene sorbitol ester.

STET  
mo  
a5

32. The process according to claim 4, wherein said first cleaning solution comprises about ~~0.0001X to 10X~~ of a ~~1X~~ detergent solution comprising about 0.066 wt % Brij-35, about 0.02 wt % Nonidet P-40, and about 0.02 wt % Nonoxynol-9 in endotoxin free water.

5  
mo  
a6

33. The process according to claim 5, wherein said second cleaning solution comprises about ~~0.0001X to 10X~~ of a ~~1X~~ detergent solution comprising about 0.066 wt % Brij-35, about 0.02 wt % Nonidet P-40, and about 0.02 wt % Nonoxynol-9 in endotoxin free water.

0.001X to 0.1X of the 1X detergent solution.

34. The process according to claim 32, wherein said cleaning solution comprises about ~~0.001X to 0.1X~~ of the ~~1X~~ detergent solution.

35. The process according to claim 33, wherein said cleaning solution comprises about ~~0.001X to 0.1X~~ of the ~~1X~~ detergent solution.

36. The process according to claim 34, wherein said cleaning solution comprises about ~~0.001X to 0.01X~~ of the ~~1X~~ detergent solution.

37. The process according to claim 35, wherein said cleaning solution comprises about ~~0.001X to 0.01X~~ of the ~~1X~~ detergent solution.  
*0.1% to 1.0% of said 100.0%*

38. The process according to claim 36, wherein said cleaning solution comprises about ~~0.005X to 0.01X~~ of the ~~1X~~ detergent solution.  
*0.5% to 1.0% of said 100.0%*

39. The process according to claim 37, wherein said cleaning solution comprises about ~~0.005X to 0.01X~~ of the ~~1X~~ detergent solution.  
*0.5% to 1.0% of said 100.0%*

40. The process according to claim 5, wherein said second cleaning solution comprises a hydrogen peroxide solution.

41. The process according to claim 40, wherein said hydrogen peroxide solution comprises about 5 to 95% ethanol or isopropanol, measured by a volume-to-volume ratio.

42. The process according to claim 41, wherein said hydrogen peroxide solution comprises about 10 to 30% ethanol or isopropanol, measured by a volume-to-volume ratio.

43. The process according to claim 3, wherein said pre-cleaning solution comprises water and at least one detergent selected from the group consisting of: an anionic detergent, a cationic detergent, and/or a non-ionic detergent.

44. The process according to claim 43, wherein said detergent is <sup>at</sup> ~~in~~ a concentration <sup>of</sup> ~~ranging~~ from about 0.001 to <sup>2.0</sup> ~~2~~ wt %.

45. The process according to claim 43, wherein said pre-cleaning solution further comprises ethanol and/or hydrogen peroxide.

46. The process according to claim 43, wherein said pre-cleaning solution comprises at least one non-ionic solvent selected from the group consisting of: a polyoxyethylene alcohol, a polyethylene glycol p-isooctylphenylether, polyoxyethylene nonylphenol, and a polyoxyethylene sorbitol ester.

47. The process according to claim 44, wherein said detergent <sup>is at a</sup> ~~concentration~~ <sup>of</sup> ~~ranges~~ from about 0.01 to 0.5 wt %.

48. The process according to any one of claims 1, 2, 16, 17, 20 or 21, wherein said process is carried out within a temperature range of about 20°C to 65° C.

49. The process according to claim 48, wherein said temperature range is from about 27°C to 55°C.

50. The process according to claim 49, wherein said temperature range is from about 37°C to <sup>44°F</sup> 42°C.

51. The process according to <sup>any one</sup> ~~any one~~ of claims 1 or 2, further comprising: monitoring solution exiting said cut bone graft to determine when essentially all of said bone marrow has been removed from said cut bone graft.

52. The process according to claim 51, wherein said monitoring comprises measuring absorbance <sup>at</sup> ~~in~~ a range of <sup>from</sup> ~~about~~ 410 nm to 700 nm.

53. The process according to claim 52, wherein said monitoring comprises measuring absorbance at 410 nm.

54. The process according to claim 51, wherein said monitoring comprises a visual monitoring of a color of solution exiting said cut bone graft.

55. A bone graft produced by the process recited in claim 1.

56. A bone graft produced by the process recited in claim 2.

57. A process for cleaning a cut bone graft, comprising:  
selecting a large, substantially intact bone;  
removing excess soft tissue from said substantially intact bone;  
cutting said substantially intact bone into one or more cut bone grafts;  
incubating said cut bone graft with one or more solutions, comprising one or more members selected from the group consisting of water, saline, a detergent, and a decontaminating agent to produce incubated cut bone grafts; and  
centrifuging said incubated cut bone grafts under conditions sufficient to remove bone marrow from cancellous bone ~~marrow~~ spaces to produce a cleaned cut bone graft suitable for transplantation into a human.

58. The process according to claim 57, further comprising:

after said step of centrifuging, second incubating said cut bone grafts with one or more solutions comprising one or more members selected from the group consisting of : water, saline, a detergent, and a decontaminating agent, to produce a second incubated cut bone graft; and

second centrifuging said second incubated bone graft under conditions sufficient to remove bone marrow from cancellous bone marrow spaces to produce a cleaned cut bone graft suitable for transplantation into a human.

59. The process according to any one of claims 1, 2, 57 or 58, wherein said centrifuging comprises centrifuging said cut bone graft at 2,000 to 3,000 rpm for 5 to 20 minutes.

60. The process according to claim 59, wherein said centrifuging is carried out at temperatures between 0°C and 45°C.

61. The process according to any one of claims 57 or 58, wherein said detergent comprises: about ~~0.0001X to 10X~~ of a ~~1X~~ detergent solution comprising about 0.066 wt % Brij-35, about 0.02 wt % Nonidet P-40, and about 0.02 wt % Nonoxynol-9, in endotoxin free water.

62. The process according to claim 61, wherein said detergent comprises about ~~0.001X to 0.1X~~ of a ~~1X~~ detergent solution.  
*0.1% to 10.0% of said 100.0%*

63. The process according to claim 62, wherein said detergent comprises about ~~0.001X to 0.01X~~ of a ~~1X~~ detergent solution.  
*0.1% to 1.0% of said 100.0%*

64. The process according to claim 63, wherein said detergent comprises about ~~0.005X to 0.01X~~ of a ~~1X~~ detergent solution.  
*0.5% to 1.0% of said 100.0%*



65. A bone graft produced by the process recited in claim 57.

66. A bone graft produced by the process recited in claim 58.

65 ~~67~~. A process for producing a cleaned cut bone graft suitable for transplantation into a human comprising:

pre-cleaning a cut bone graft with a pre-cleaning solution to produce a pre-cleaned cut bone graft;

incubating said pre-cleaned cut bone graft in a cleaning solution to produce a cleaned cut bone graft; and

centrifuging said cleaned cut bone graft to produce a centrifuged cut bone graft essentially free from bone marrow.

66 ~~68~~. The process of claim 2, further comprising:  
after said step of centrifuging, incubating said centrifuged cut bone graft in a cleaning solution to produce a cleaned cut bone graft;

washing said cleaned bone graft in a washing solution to produce a washed cut bone graft; and

centrifuging said washed cut bone graft to produce a cut bone graft essentially free from bone marrow.

67 ~~69~~. A process for producing a cleaned cut bone graft suitable for transplantation into a human, comprising:

pre-cleaning a cut bone graft with a pre-cleaning solution to produce a pre-cleaned cut bone graft;

cleaning said pre-cleaned cut bone graft with a cleaning solution to produce a cleaned cut bone graft;

centrifuging said cleaned cut bone graft to produce a centrifuged bone graft;

washing said centrifuged bone graft with a washing solution to produce a washed bone graft;

incubating said washed bone graft with water to produce a water washed cut bone graft; and

centrifuging said water washed cut bone graft to produce a cut bone graft essentially free from bone marrow.

5 70. A cleaned cut bone graft suitable for transplantation into a human, wherein said cleaned cut bone graft is essentially free from viral contamination.

71. A cleaned cut bone graft suitable for transplantation into a human, wherein said cleaned cut bone graft is essentially free from bacterial contamination.

72. A cleaned cut bone graft suitable for transplantation into a human, wherein said cleaned cut bone graft is essentially free from viral and bacterial contamination.

73. The cleaned cut bone graft of claim 70 produced by the process as claimed in claim 1.

74. The cleaned cut bone graft of claim 71 produced by the process as claimed in claim 1.

15 75. The cleaned cut bone graft of claim 72 produced by the process as claimed in claim 1.

76. A cleaned cut bone graft suitable for transplantation into a human, wherein said cleaned cut bone graft is essentially free from fungal contamination.

20 77. A cleaned cut bone graft suitable for transplantation into a human, wherein said cleaned cut bone graft is essentially free from bacterial, viral and fungal contamination.

78. The cleaned cut bone graft of claim 70 produced by the process as claimed in claim 1.

79. The cleaned cut bone graft of claim 77 produced by the process as claimed in claim 1.

80. The cut bone graft of anyone of claims 57, 58, 67, 68 or 69, wherein said bone grafts is the essentially force from viral, bacterial and fungal contamination.

81. A holding device for cleaning a femoral or humeral head, comprising:  
a disk having a large bore hole centrally located on said disk, and a plurality of small bore holes disposed toward a perimeter of said disk  
one or more support rods slidably disposed within said small bone holes, and  
at least one set screw disposed through a side wall of said disk into said large bore hole,  
wherein said set screw holds said femoral or humeral head in place.

82. A holding device for cleaning a cut bone graft, comprising:  
a first and a second rigid porous disk, each rigid porous disk having a plurality of bore holes disposed at a perimeter of said disk;  
a first and second pliant porous disk;  
a plurality of supports rods slidably disposed in said bore holes, and  
at least one set screw disposed through a side wall of said rigid porous disk into a bore hole,

wherein during use a cut bone graft is sandwiched between said first and second pliant porous disks to form a unit and said unit is sandwiched between said rigid porous disks, said unit is configured to fit within a diameter as defined by said support rods, said support rods are slidably disposed within said bore holes of said first and second rigid porous disks and held in place by said at least one set screw.

83. The holding device of anyone of claims 81 and 82 wherein said holding device further comprises:

a bottle comprising a cylindrical vessel having a closed bottom end and an open top end, and a lid having a bore hole therethrough;

wherein during use said holding device is disposed within said centrifuge bottle and said lid is fitted over said open end of said vessel.

84. The holding device of claim 83, further comprising:  
a filter disposed within said bore hole of said lid.

